K093113

4. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

DEC 18 2009

Submitter

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Date:	September 25, 2009

Name of Device

Proprietary Name:	etkon™ es1 etkon™_visual Straumann CARES
Classification Name:	Optical Impression Systems for CAD/CAM Endosseous Dental Implant Abutment
Common Name:	3D Dental Lab Scanner Dental Restoration Design Software Dental Abutment

Predicate Devices

Straumann Computer-aided Restoration (C.A.R.E.S.) Ceramic Coping	K061277
Straumann NN CARES Titanium and Ceramic Abutments	K082545
Straumann WN CARES Titanium Abutment	K082764
P.004 NC CARES Titanium and Ceramic Abutments	K081005

P.004 RC CARES..... K072151
Titanium and Ceramic Abutments

Straumann Computer aided..... K052272
Restoration Service

Procera® Software K053602
Nobel Biocare AB

Description for the Premarket Notification

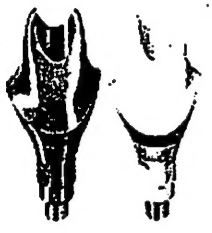
etkon™_visual is a software package by Institut Straumann AG which allows for digital design of customized abutments.

etkon™_visual is also the operating software that controls Straumann's scanner etkon™ es 1. The scanner etkon™ es 1 together with the application software etkon™_visual fall under the definition of 21CFR872.3661, Optical Impression Systems for CAD/CAM. Such systems are defined as class II devices which are exempt from 510(k) requirements.

This 510(k) premarket notification submission describes etkon™_visual's dental abutment design functionality.

For designing a dental abutment, the etkon™ es 1 scanner collects data from a dental plaster model with a scan body attached intended to provide for the correct positioning of the abutment. The scanning is done extraorally. The scan data is used by the etkon™_visual software design tools to virtually design the shape and size of the dental abutment. Once the design process is finished, the digital dataset is sent to Straumann by internet connection for CAM manufacturing from milling blanks.

The individual abutments that are finally manufactured at Straumann from zirconium dioxide and titanium blanks meet all properties and specifications of Straumann's already 510(k)-cleared individual abutments ("CARES") as listed above in the "Predicate Devices" paragraph.



Verification and validation efforts of etkon™_visual provides evidence that design parameters for the individual abutments are met and that dental abutments meeting design specifications are manufactured by Straumann.

In its functionality, etkon™_visual is substantially equivalent to Nobel Biocare's Procera® Software.

In summary, it can be concluded that safety and effectiveness requirements for etkon™_visual for the design of individual dental restorations including abutments are completely met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Institut Straumann AG
C/O Dr. Andreas Petermann
Head of Regulatory Affairs
Straumann CADCAM GmbH
Lochhamer Schlag 6
Graefelfing, Bavaria 82166
GERMANY

JUN 23 2010

Re: K093113
Trade/Device Name: Etkon_Visual
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA, NOF
Dated: September 25, 2009
Received: October 1, 2009

Dear Dr. Petermann:

This letter corrects our substantially equivalent letter of December 18, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

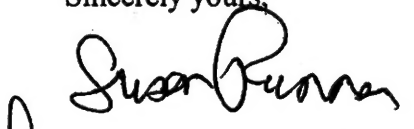
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: etkon_visual

Indications For Use: etkon_visual is a software device intended to import patient-specific data from a scanner for CAD (computer aided design) design of individual dental restorations like crowns, bridges, inlays, onlays, veneers and abutments.
etkon_visual also facilitates the transfer of 3D data from a dental lab to a remote milling center by internet connection and serves as an order management tool.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R S Better DDS for Dr. K.P. Mulay (Acting)
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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